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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,797	03/15/2000	Athanasius A Anagnostou	5218-39B	9917

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/525,797	ANAGNOSTOU ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *March 28, 3005*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *12-15,19-21,23-26 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *12-15, 19-21, 23-26, 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed March 28, 2005 in response to the Office Action of January 28, 2005 is acknowledged and has been entered. Previously pending claims 12 and 21 have been amended, claims 27-30 have been cancelled, and new claims 31-33 have been added. Claims 12-15, 19-21, 23-26, 31-33 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC 103

4. Claims 12-15, 19-21, 23-26 remain rejected under 35 USC 103 and new claims 31-33 are rejected under 35 USC 103 for the reasons previously set forth in the paper mailed January 28, 2005, Section 9, pages 7-9.

Applicant argues that one would not have a reasonable expectation of success of treating patients with cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx because the patients described in Bukowski et al are anemic cancer patients. The argument has been considered but has not been found persuasive because treatment of Bukowski et al is clearly a pan cancer treatment, the subjects that are treated in the Bukowski et al study include a broad variety of cancer patients including patients who have solid vascularized tumors who are in need of the treatment as claimed. Since Bukowski et al teaches a pan tumor treatment for vascularized tumors and since cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx are solid vascularized tumors, one would have had a reasonable expectation of success for the reasons previously set forth.

Applicant further argues that Bukowski et al alleges that a non-specific cancer patient population experienced improved energy level, activity level and overall well-being which are indications that their anemic condition may have improved. Thus, the study is directed to improving symptoms and clinical outcomes associated with anemia and does not provide motivation to modify the protocol to provide treatment of solid vascularized tumors as recited in the claims of the present application. The argument has been considered but has not been found persuasive because although these clinical outcomes are outcomes in the treatment of anemia, Examiner is sure that Applicant is aware that these outcomes are also the outcomes from successful treatment of solid vascularized tumors.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC 102

5. In order to clarify the record, Claims 12-15, 19-21, 23-27, 31-33 are rejected under 35 USC 102(b) for the reasons previously set forth in the paper mailed December 28, 2004, Section 6, pages 3-7 and further for the reasons set forth below.

It is noted that Bukowski et al, of record, specifically state that the cisplatin study population consisted of 441 chemotherapy patients with various tumor types from community-based oncology practices nationwide, thus it is clear that the treatment protocol is a pan cancer treatment protocol across a wide variety of cancers, including any and all solid vascularized tumors and thus the instant reference anticipates this treatment for any and al cancers including any and all solid vascularized tumors.

The claims are drawn to a method of treating a solid vascularized tumor in a subject in need of such treatment comprising administering cisplatin in conjunction with erythropoietin in an amount effective to enhance suppression of endothelial growth associated with administration of cisplatin wherein the subject is afflicted with a solid vascularized tumor selected from cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx (claim 12), wherein said erythropoietin is administered concurrently with cisplatin (claim 13), prior to cisplatin (claim 14),after cisplatin (claim 15), wherein said cisplatin is administered intravenously (claim 19), wherein said erythropoietin is administered intravenously (claim 20), a method of treating a solid vasularized tumor comprising administering cisplatin in conjunction with erythropoietin wherein the erythropoietin is administered in an amount from about 750 U/Kg to about 2,000 U/kg and said subject is afflicted with a solid vascularized tumor selected from cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx (claim 21), wherein said erythropoietin is administered concurrently with cisplatin (claim 23), wherein said cisplatin is administered intravenously (claim 24), wherein said erythropoietin is administered intravenously (claim 25), wherein said cisplatin is administered IV, IM, IP, SC, IT or IP (claim 26), a method of treating a condition/a solid vascularized tumor, associated with abnormal angiogenesis in a subject comprising administering erythropoietin in conjunction with a chemotherapeutic agent, wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial growth (claim 27), wherein said chemotherapeutic agent is cisplatin (claim 29).

Bukowski et al teach as set forth previously, that is, Bukowski et al teach a successful pan cancer phase IV study wherein erythropoietin was administered sc

to 441 cancer patients in conjunction with cisplatin, wherein improvement in quality of life parameters was found wherein the patients experienced improved energy level, activity level and overall well-being, wherein transfusion requirements were reduced wherein the patients are treated with 150 U/kg sc three times a week for 8 weeks so that by the end of week 2 the patients had received 900 U/kg of erythropoietin and by the end of week 5 the patients had received about 2000 U/kg of erythropoietin. Since the specification does not teach a specific time for the administration of the erythropoietin and the claims are not limited to a specific time, the instant reference meets the dosage limitation of the claims. Further, since the reference teaches that the patients were receiving concomitant chemotherapy regimens, the erythropoietin was clearly being administered concurrently, prior to and after cisplatin administration. The method of the prior art comprises the same method steps as claimed in the instant invention, that is administering erythropoietin in conjunction with cisplatin to the same population, that is patients with solid vascularized tumors at the same dosage, thus the method is anticipated because the method will inherently lead to the enhanced suppression of endothelial growth associated with the administration of cisplatin. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Further, it is noted that the specification admits on the record that methods of administering chemotherapeutic drugs vary depending upon the specific agent used and would be known to one skilled in the art (p. 10, lines 24-29). One of skill would immediately envision the intravenous administration of both cisplatin and erythropoietin.

Applicant's arguments drawn to the rejection of claims 12-15, 19-21, 23-27 in the paper mailed December 28, 2004, Section 6, pages 3-7 are relevant to the instant rejection.

Applicant argues that the patient population as indicated in the present application is not the same as that of Bukowski et al, in particular, the patient population in Bukowski et al is anemic cancer patients and the cancers treated include hematologic and non-hematologic tumor types. Thus, in view of the different patient populations subjected to the treatment, the method described in Bukowski et al would not inherently lead to enhanced suppression of endothelial growth associated with administration of cisplatin in the distinct patient population intended in the present invention. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted as the claims are drawn to treating solid vascularized tumor in a subject in need of such treatment and although the claims are not drawn specifically to anemic cancer patients, the claims as currently constituted are not drawn to a distinct patient population as apparently intended in the present invention as they do not exclude anemic cancer patients. Further, the subjects that are treated in the Bukowski et al study include patients with not only hematologic but also non-hematologic tumor, that is solid vascularized tumors. Thus it is clear that the treatment taught is a pan cancer treatment, effective for all types of tumors and thus anticipates said treatment for any and all cancers.

Applicant argues that the Office Action states that "Bukowski et al 'does not spsecifically teach that patients with various types of cancer include cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the Larynx' at page 7. The argument has been considered but has not been found

persuasive because Applicant is mischaracterizing Examiner's statement by leaving out the preamble to that statement wherein in fact Examiner wrote that "To the extent that Bukowski et al, Supra, does not specifically teach that the patients with various types of cancer include cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx". The statement was not drawn to the rejection under 35 USC 102(b), but rather was drawn to the rejection of the claims under 35 USC 103. The arguments have been considered but have not been found persuasive.

6. All other objections and rejections recited in the previous action are hereby withdrawn.

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
June 6, 2005